Wolf, Greenfield & Sacks, P.C.
Federal Reserve Plaza
600 Atlantic Avenue
Boston, Massachusetts 02210
(617) 720-3500
Fax (617) 720-2441

FAX COVERSHEET

February 13, 2004

Number of Pages (including coversheet):	16
For the Attention of:	European Patent Office
Fax Number:	011 49 89 2399 4465
Re: International Application No.:	PCT/US03/34828
International Filing Date:	31 October 2003 (31.10.2003)
Earliest Priority Date:	31 October 2002 (31.10.2002)
Applicant(s):	C.R. BARD, INC. ET AL.
Title:	IMPROVED ELECTROPHYSIOLOGY LOOP
Our Reference No.:	B1075.70032

CERTIFICATION OF FACSIMILE TRANSMISSION

The undersigned hereby certifies that a Request Under PCT Rule 91.1(b) for Rectification of Obvious Errors with substitute sheet(s) are being facsimile transmitted to European Patent Office, Erhardtstrasse 27, D-80298 Munich, GERMANY, on 13 February 2004.

Colleen F. Sullivan
Name

Colleen F. Sullivan
Signature

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IN THE EUROPEAN PATENT OFFICE
AS INTERNATIONAL SEARCHING AUTHORITY

International Application No.	:	PCT/US03/34828
International Filing Date	:	31 October 2003 (31.10.2003)
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Title	:	IMPROVED ELECTROPHYSIOLOGY LOOP CATHETER

European Patent Office
Erhardtstrasse 27
Munich D-80298
GERMANY

REQUEST UNDER PCT RULE 91.1(b)
FOR RECTIFICATION OF OBVIOUS ERRORS

Transmitted herewith for filing is a Request Under PCT Rule 91.1(b) for Rectification of Obvious Errors with substitute sheets.

If the enclosed papers are considered incomplete, the Authorized Officer is respectfully requested to contact the undersigned collect at (617) 720-3500, Boston, Massachusetts.

Respectfully submitted,

James H. Morris
Reg. No.: 34,681
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
Facsimile: (617) 720-2441

DOCKET NO.: B1075.70032
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REQUEST UNDER PCT RULE 91.1(b)
FOR RECTIFICATION OF OBVIOUS ERRORS

Applicant would like to bring to the Authorized Officer's attention that changes have been made to the above-identified international application.

In the Specification

Page 11, line 23, replace "side elevational" with --perspective-- for clarification;

Page 11, line 25, replace "side elevational" with --perspective-- for clarification;

Page 12, line 13, replace "elevational" with --perspective-- for clarification;

Page 12, line 18, replace "elevational" with --perspective-- for clarification;

Page 28, line 16, after "Figure", replace"140" with --1—for clarification;

Page 35, line 24, replace "6610a-b" with --6620a-b-- for clarification;

Page 35, line 25, replace "6610a-b" with --6620a-b-- for clarification;

Page 54, line 5, replace "44" with --54-- for clarification;

Page 56, line 7, replace "51" with --61-- for clarification;

Page 56, line 9, replace "50" and "51" with --60-- and --61-- respectively, for clarification;

Page 63, line 27, after "line", replace "A-A" with --36-36-- for clarification.

In the Drawings

Fig. 40A, add reference numerals 142 and 148;

Fig. 40B, add reference numeral 142;

Fig. 56, add reference numeral 147;

Fig. 62A, change reference numeral "6240" to --6250--;

Fig. 62A, add reference numeral 6260;

Fig. 62B, change reference numeral "6240" to --6350--;

Fig. 63, change reference numeral "6230" to --6330--;

Fig. 63, change reference numeral "6240" to --6350--;

Fig. 63, add reference numeral 6360;

Fig. 67, add reference numeral 148

Fig. 69, change reference numeral "6830" to --6930--;

Replacement sheets of Pages 11, 12, 28, 35, 54, 56 and 63 are enclosed and replacement Figures 40A, 40B, 56, 62A, 62B, 63, 67, and 69 are also enclosed. Applicant respectfully requests that these replacement sheets and figures be accepted and replace originally filed Pages 11, 12, 28, 35, 54, 56 and 63 and Figures 40A, 40B, 56, 62A, 62B, 63, 67, and 69 to reflect the changes. No new matter has been added.

REMARKS

The Authorized Officer is invited to contact the undersigned by collect telephone call should he/she have any questions concerning this Request.

Respectfully submitted,

James H. Morris
Reg. No.: 34,681
WOLF, GREENFIELD & SACKS, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210
United States of America
Telephone: (617) 720-3500
Facsimile: (617) 720-2441

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Figures 44A and 44B are schematic views illustrating a third configuration for controlling the proximal end of the tip assembly with a superelastic wire and a pull wire;

Figure 45 is an enlarged end elevational view of the distal end tip assembly according to another embodiment of the invention in which an adhesive is used to bias the orientation of the tip assembly;

Figures 46A and 46B are schematic views illustrating a first configuration for controlling the distal end of the tip assembly with a cured adhesive and a pull wire;

Figures 47A and 47B are schematic views illustrating a first configuration for controlling the proximal end of the tip assembly with a cured adhesive and a pull wire;

Figures 48A and 48B are schematic views illustrating a second configuration for controlling the distal end of the tip assembly with a cured adhesive and a pull wire;

Figures 49A and 49B are schematic views illustrating a second configuration for controlling the proximal end of the tip assembly with a cured adhesive and a pull wire;

Figures 50A and 50B are schematic views illustrating a third configuration for controlling the distal end of the tip assembly with a cured adhesive and a pull wire;

Figures 51A and 51B are schematic views illustrating a third configuration for controlling the proximal end of the tip assembly with a cured adhesive and a pull wire;

Figure 52 is a schematic view illustrating the distal end of the tip assembly according to another embodiment of the invention in which an adhesive is used to impart a fixed bias to the orientation of the tip assembly;

Figure 53 is a schematic view illustrating the proximal end of the tip assembly according to the embodiment of Figure 52;

Figure 54 is a perspective view of a tip assembly including multiple localization sensors in accordance with another embodiment of the present invention;

Figure 55 is a perspective view of a tip assembly including a movable electrode assembly with a localization sensor in accordance with another embodiment of the present invention;

Figure 56 is a side view of a tip assembly including a fluid delivery structure in accordance with another embodiment of the present invention;

Figure 57 is a side view of a tip assembly including a fluid delivery structure in accordance with further embodiment of the present invention;

Figure 58 is a cross sectional view of the tip assembly of Figure 56 taken along line 58-58 in Figure 56;

Figure 59 is a cross sectional view of the tip assembly of Figure 57 taken along line 59-59 in Figure 57;

Figure 60 illustrates the delivery of fluid into the heart via the distal tip of the catheter in accordance with an embodiment of the invention;

Figure 61 illustrates the delivery of fluid into the heart via the proximal end of the tip assembly of the catheter in accordance with another embodiment of the invention.

Figures 62A and 62B illustrate a catheter including a fluid delivery structure in accordance with another embodiment of the present invention;

Figure 63 illustrates a sheath including a fluid delivery structure in accordance with an embodiment of the present invention;

Figures 64A is a fragmentary perspective view illustrating the proximal end of the tip assembly according to another embodiment of the invention in which an adhesive is used to provide support to the tip assembly;

Figure 64B is a schematic view illustrating control of the proximal end of the tip assembly according to the embodiment of Figure 64A;

Figures 65A is a fragmentary perspective view illustrating the distal end of the tip assembly according to another embodiment of the invention in which an adhesive is used to provide support to the tip assembly;

Figure 65B is a schematic view illustrating control of the distal end of the tip assembly according to the embodiment of Figure 65A;

Figure 66 is a perspective view of a distal tip assembly illustrating an exemplary location where superelastic channels may be located in the distal tip assembly;

Figure 67 illustrates a cross sectional view of the distal tip assembly shown in Fig. 66;

Figure 68 is a perspective view of a portion of one exemplary implementation of a superelastic channel;

Figure 69 is a perspective view of a portion of another exemplary implementation of a superelastic channel;

Figure 70 is an elevational view of a superelastic channel;

Figure 71 is a schematic view illustrating a configuration for controlling the proximal end of a tip assembly having a superelastic channel using a pull wire; and

Figures 43A and 43B illustrate a configuration similar to that shown in Figures 41A and 41B. However, rather than being biased in an arcuate curve, superelastic wire 3810 is biased linearly and causes the distal end 144 of the tip assembly 140 to assume a linear orientation when no tension is applied to pull cable 1110b (see Figure 43A). When tension is applied to cable 1110b, as shown in Figure 43B, the radius of curvature of the distal end 144 of the tip assembly 140 decreases, causing the distal end 144 of the tip assembly 140 to assume an arcuate curve.

According to another embodiment of the invention, adhesive may be introduced into the catheter 100 (Figure 1) and cured in a configuration such that it imparts a bias on the catheter 100 or tends to retain a portion of the catheter 100 in a particular position or shape. For example, the adhesive may be injected into a lumen of the catheter 100, e.g., by means of a syringe, and a portion of the catheter 100 may be placed in a jig, such as the jigs described in connection with Figures 5-10. The jig holds the catheter 100 in a desired position while the adhesive cures so that the catheter 100 with the cured adhesive is biased in a particular orientation. According to another aspect of the invention, the adhesive may be used in connection with a pull cable to provide control of the tip assembly 140 (Figure 1). Epoxy and silicone are two exemplary adhesives that may be used in accordance with the present embodiment. Other adhesives that are compatible with the catheter material and that impart a bias or that tend to retain their shape when cured may also be used. Various configurations of the catheter 100 including an adhesive to provide a bias will be described below.

Figure 45 is an enlarged elevational view of the distal end tip assembly 140 of Figure 2 implemented in accordance with the present embodiment of the invention. As shown in Figure 45, the distal end 144 of the tip assembly 140 includes adhesive 4510 within lumen 1128b that has been cured in an arcuate shape. When used with cable 1110a, the adhesive 4510 may be used to change the radius of curvature of the tip assembly from a first radius to a second radius, as will be described.

It should be appreciated that while the adhesive 4510 is shown extending along the length of the distal end 144 of the tip assembly 140 through lumen 1128b, the adhesive 4510 may be disposed in other portions of the catheter 100. For example, the adhesive 4510 may be disposed within the central lumen 1125 or another lumen of the tip assembly 140. Further, the adhesive 4510 may extend through any portion of the catheter 100 sufficient to bias the distal end 144 of the tip assembly 140 is a desired arcuate shape. For example, the adhesive

Superelastic Channels

Figures 66-72 illustrate a further embodiment of the invention according to which a superelastic channel may be used to impart a bias to a portion of the catheter having a particular configuration, such that the portion will "spring back" to the configuration after being deformed. In one example, a superelastic channel may be incorporated within a portion of a lumen of the catheter to bias the catheter in a particular configuration while allowing a catheter component (e.g., a pull cable, wire, or fluid conduit), or multiple such catheter components, to pass through the portion of the lumen. In another example, a superelastic channel may be incorporated within the catheter, but not within a lumen. For instance, the channel may form part of the exterior sheath of the catheter, or may be an interior channel that at least partially encloses many structures (e.g., lumens) in the catheter.

In one example, illustrated in Figures 66-67, superelastic channels 6620a-b are included in the portion of the tip assembly 140 that includes bend 148, which is described herein as being an approximately ninety degree bend, but which may have an angle that is greater or less than ninety degrees. The channels 6620a-b are included within lumens 1128a and 1128b, respectively, and extend from a location 6610a at the proximal end 142 of the tip assembly 140 to a location 6610b at electrode 146b. Thus, in one example, channels 6620a-b extend from the proximal end 142 of the tip assembly 140 to a portion of the distal end 144 of the tip assembly 140, which may be biased to form a curve. The channels 6620a-b may be held in place by the lumens 1128a-b themselves, or may be adhered to the lumens, e.g., with epoxy between each channel and lumen near location 6610a. The channels 6620a-b bias the portion of the catheter spanning locations 6610a and 6610b to form the configuration of ninety degree bend 148 and to "spring back" to the configuration after being deformed. Thus, channels 6620a-b form a resilient bend angle in tip assembly 140. It should be appreciated, however, that channels 6620a-b may be used in connection with other biasing mechanisms (e.g., heating in a jig) and/or resiliency mechanisms (e.g., superelastic wires) to achieve the desired bias or resiliency.

Many variations on the configuration shown in Figures 66-67 are possible to achieve a resilient bend angle in tip assembly 140 using superelastic channels. For example, channels 6620a-b may occupy any of the lumens 1128a-d described herein, or one or more additional lumens. Further, although two channels are illustrated, a single channel or greater than two channels (e.g., three, four, five, or more) may alternatively be employed. In addition, while

of Figure 1. The wire 4530 may be insulated, and may be coupled to the push/pull wire 1920 shown in Figure 19.

It should be appreciated that the electromagnetic sensor 3450c may be used with one or more additional sensors such as electromagnetic sensors 3450a and 3450b described in connection with Figure 54. It should also be appreciated that the electromagnetic sensors 3450a-c may be implemented as described for the electromagnetic sensor 3450, or alternative localization techniques may be used in place of the electromagnetic sensors 3450a-c, such as the ultrasound, MRI, and impedance-based sensor localization techniques described in connection with electromagnetic sensor 3450.

Fluid Delivery

As the catheter 100 described herein may be used in connection with medical imaging and/or fluoroscopy, it may be desirable to deliver a contrast agent (e.g., a bolus of x-ray contrast agent or radio-opaque dye) to the cardiovascular system during an electrophysiology procedure. Further, it may be desirable to administer drugs such as antithrombogenic agents directly to the cardiovascular system during a catheter procedure. Figures 56 and 58 illustrate one embodiment of a structure to deliver fluids, such as drugs and contrast agents, that may be incorporated into embodiments of the catheter 100 described herein. As shown, the tip assembly 140 includes a first and second fluid delivery lumens 4640 and 4610. The first fluid delivery lumen 4640 is disposed within the central lumen 1125 of the catheter 100, while the second fluid delivery lumen 4610 is embedded within the core 1120 of the catheter 100. The second fluid delivery lumen 4610 may be any of the coaxial lumens 1128a-d described previously, or may be an additional lumen. The first and second fluid delivery lumens 4640 and 4610 may have respective dimensions chosen to provide, either individually or in combination, an adequate flow of fluid therethrough. For example, in one implementation, the combined cross-sectional area of the fluid delivery lumens may be chosen to be equivalent to a cylindrical lumen having a diameter between approximately 0.025 inch and approximately 0.039 inch. Opening 4650 on the distal tip 147 of the catheter 100 and opening 4620 on the circumferential surface of the catheter 100 are respectively provided for the first and second fluid delivery lumens. Opening 4620 includes an angled surface 4630 to direct the direction of fluid exit from the catheter 100.

which may be joined at the proximal opening 6360. Fluid may exit the sheath 2120 through one or more distal openings 6350 disposed at the distal end of the sheath.

Figures 60 and 61 illustrate the delivery of fluid from the catheter 100 into the heart. In Figure 50, the catheter 100 is shown traversing the septal wall of the heart from the right atrium 3610 into the left atrium 3620. Fluid 5010 is ejected from the tip of the distal end 144 of the catheter 100 into the left atrium 3620. As discussed above, fluid 5010 may be a drug or a contrast agent. In Figure 61, fluid 5010 is ejected from an opening 4620 in the proximal end of the tip assembly 140 into the left atrium 3620. Although the fluid 5010 is shown being injected into the left atrium 3620 in both Figures 60 and 61, it should be appreciated that the fluid 5010 may alternatively be injected into the pulmonary vein 3710, into another blood vessel, or into the right atrium 3610 or ventricles.

Methods For Making The Tip Assembly

Figures 5-10 illustrate a number of different jigs that may be used to form a tip assembly having a fixed bend of approximately ninety degrees followed by an arcuately curved distal end. Each of these jigs may be used with a finished catheter (i.e., a catheter which is already fully assembled, and including a handle 120 and electrodes 146, 147 disposed on the distal end of the tip assembly 140), a partially finished tip assembly (i.e., a tip assembly 140 that includes electrodes 146, 147, that is not yet attached to shaft 110 and the handle 120 (Figure 1)), or an unfinished tip assembly 140 (i.e., a tip assembly 140 without any electrodes 146, 147).

Figures 5 and 6 illustrate a first jig 500 that is formed from a hollow tube. In one embodiment, the hollow tube is formed from hypodermic stainless steel tubing, although other materials, such as a high temperature plastics such as TEFLON, DELRIN, etc., may alternatively be used. The material from which the jig 500 is formed should be thermally stable, such that its shape does not change when subjected to temperature in the range of 200-400 degrees Fahrenheit. In one embodiment, the tube used to form the jig 500 has an outer diameter of approximately 0.83 inches and an inner diameter of approximately 0.72 inches to accommodate a tip assembly 140 that is approximately 6 French in diameter, although these dimensions may be varied to accommodate different diameter tip assemblies. For example, to accommodate a tip assembly that is 10 French in diameter, a larger diameter tube would be used. As shown in Figure 5, the distal end of the jig 500 is formed in a circle having an inner

Preferably, multiple electrodes are employed, such that multiple electrograms may be obtained simultaneously. This allows for multiple data points, which can result in a more precise mapping of the heart signal and a shorter required measurement time. A shorter measurement time advantageously reduces the x-ray exposure to patients and physicians during fluoroscopy, when employed during the catheter procedure.

The mapping function of the catheter can be used for a number of different applications. For example, in one application, the catheter may be used to measure the conductivity at various points of the septal wall, which separates the left and right sides of the heart, to determine a preferred sight for puncture of the septal wall. In another application, the conductivity of the heart tissue may be measured between adjacent electrodes in contact with the heart tissue to determine the continuity of a lesion formed by ablation. In still another application, the catheter may used to identify electrical signals within the heart that are characteristic of a number of heart conditions. For example, the focus site of an arrhythmia (e.g., atrial fibrillation, AV nodal tachycardia or tachycardia resulting from Wolff-Parkinson-White syndrome).

Reference is now made to Figure 35, which illustrates a method of insertion of the catheter 100 into a patient 3510 in accordance with an embodiment of the present invention. The catheter 100 is inserted into the patient via a blood vessel, e.g., subclavian vein, jugular vein, or femoral vein. In Figure 35, the catheter 100 is shown entering a femoral vein 3520 via an incision 3530 in the thigh of the patient 3510. The catheter 100 may be introduced into the vein using a sheath/dilator (not shown). The sheath/dilator may be anchored at the incision site, for example by stitching the sheath/dilator to the patient's skin at the area of incision 3530. From the incision site 3530 in the femoral vein 3520, the catheter 100 may be advanced independently, or through a sheath/dilator, up the inferior vena cava 3540 into the right atrium of the heart.

Reference is now made to Figure 36, which illustrates a diagram of a cross-sectional view of the heart taken along line 36-36 in Figure 35. The catheter 100 is shown entering the right atrium 3610 via the inferior vena cava 3540. For passage of the catheter 100 into the left atrium , 3620 the distal end of the catheter 100 may be passed trans-septally through the septal wall 3630. In one method, a puncture 3640 in the septal wall 3630 is made at the foramen ovale, an area of the septal wall having a decreased thickness and decreased conductivity relative to other areas of the septal wall. As described previously, electrodes on

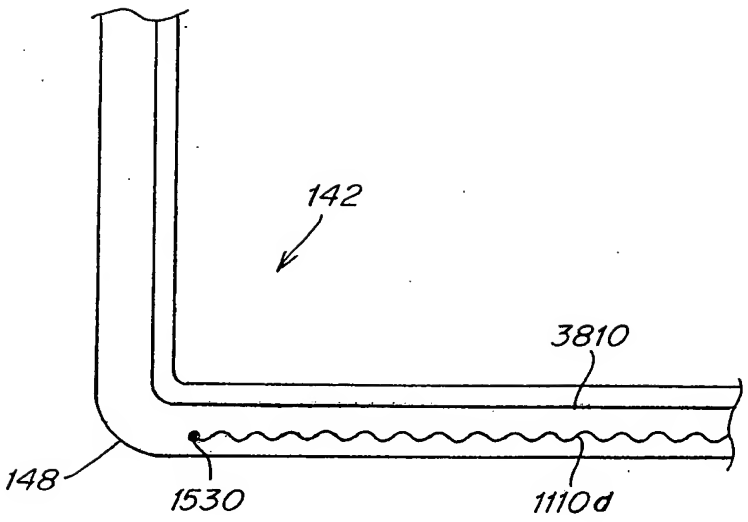


Fig. 40A

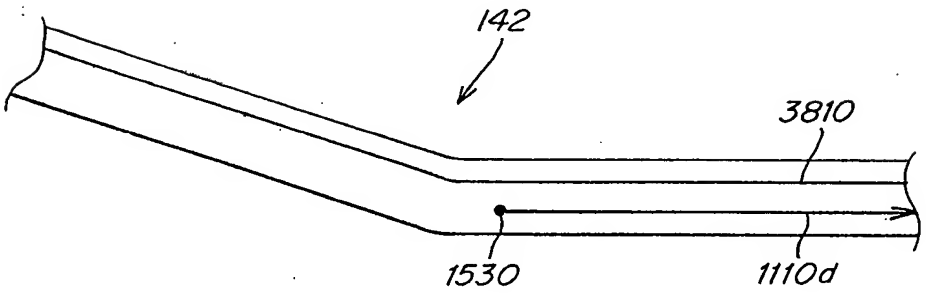


Fig. 40B

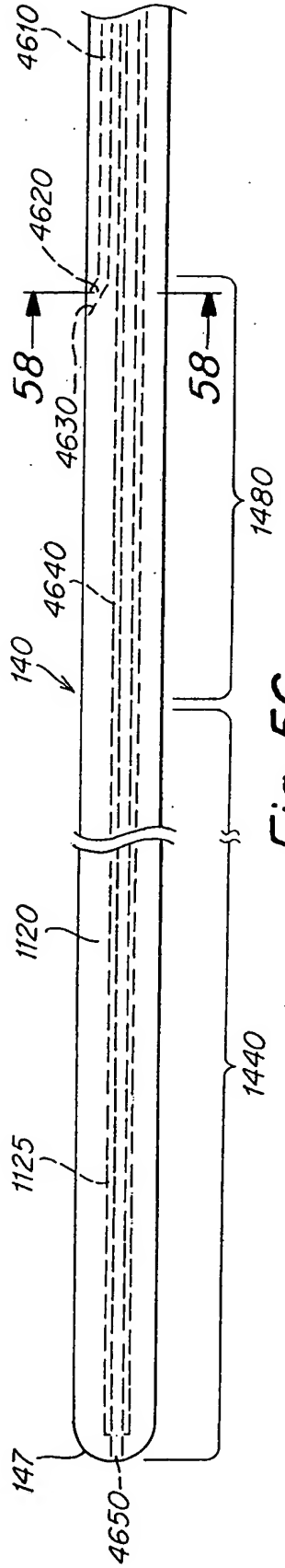


Fig. 56

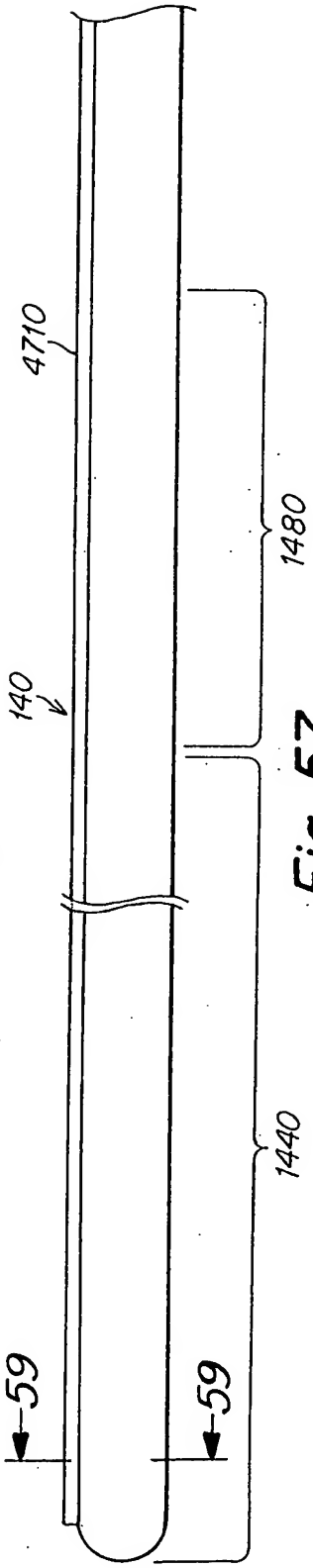


Fig. 57

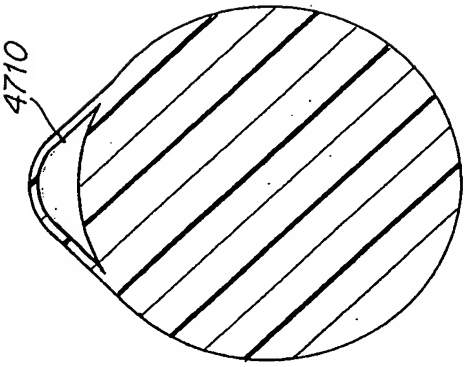


Fig. 59

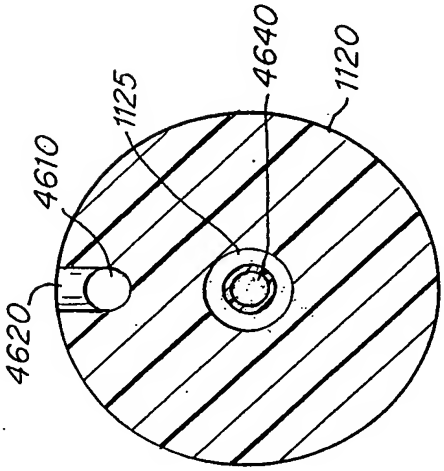


Fig. 58

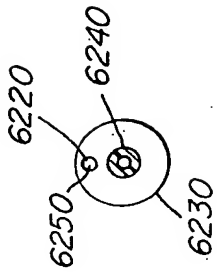


Fig. 62B

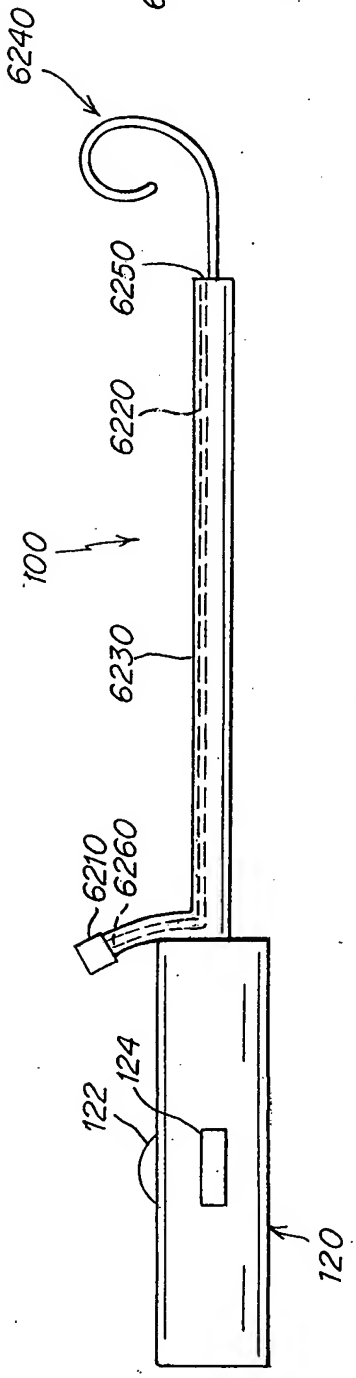


Fig. 62A

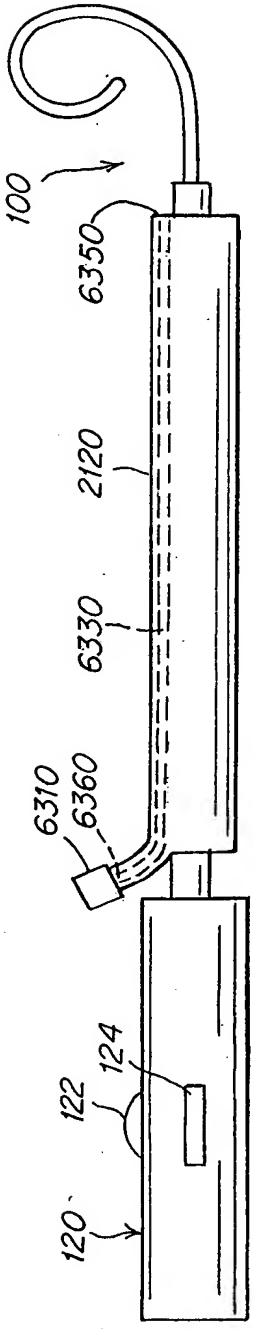
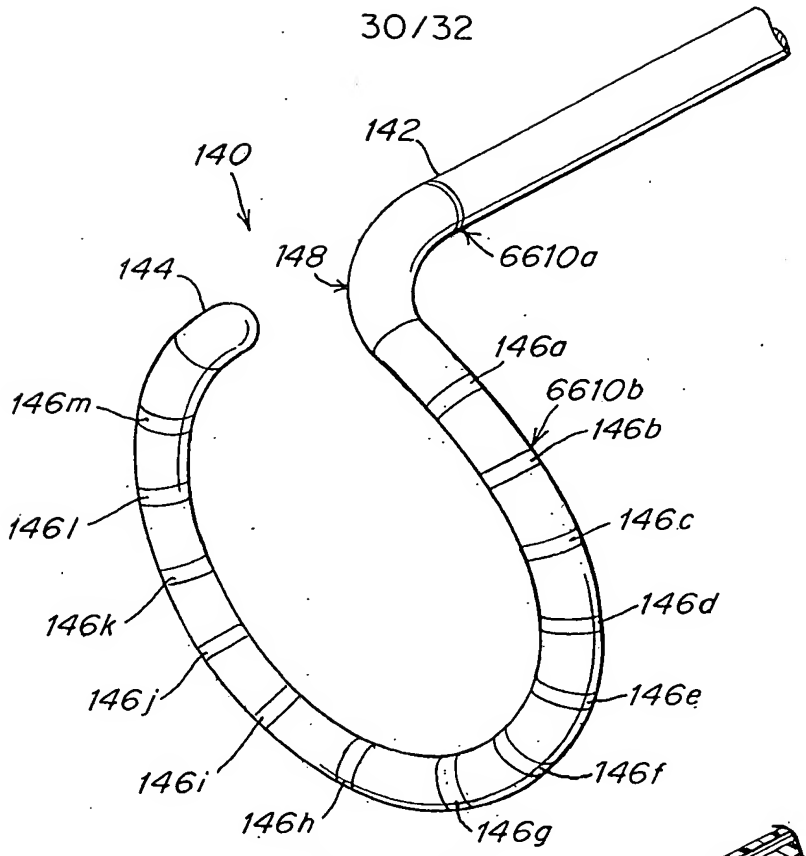


Fig. 63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146a
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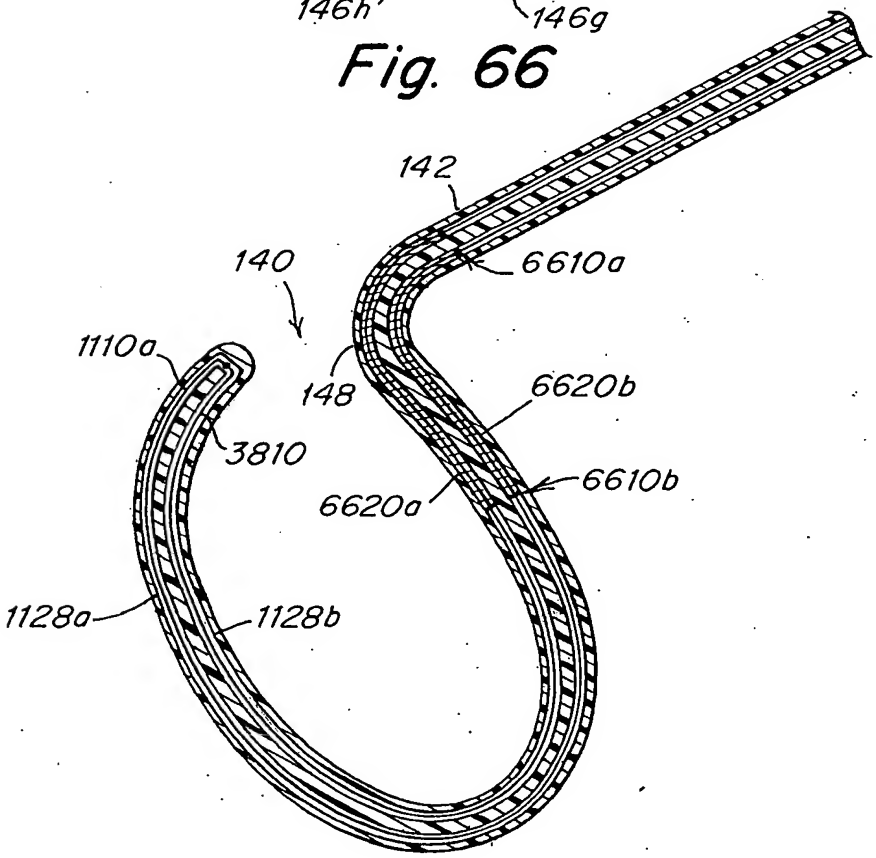
Fig. 66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3810
6610b
6620a
1128a
1128b

Fig. 67

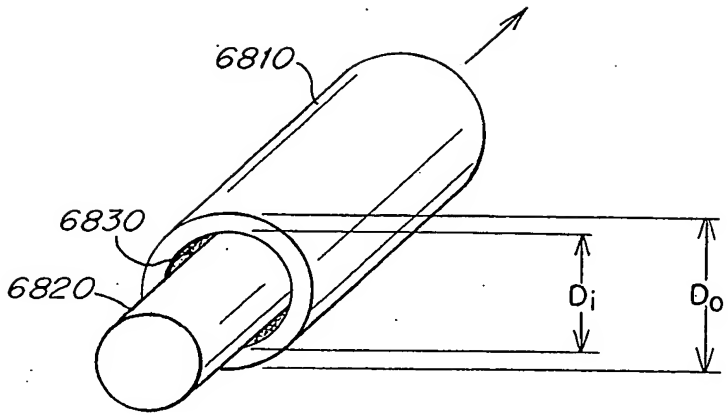

Fig. 68

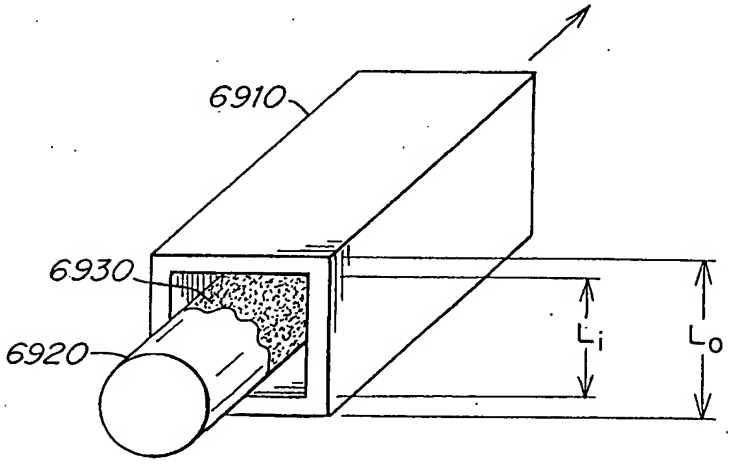

Fig. 69

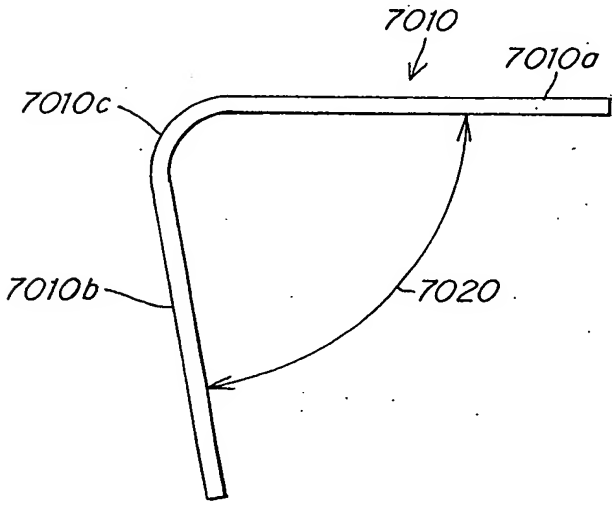

Fig. 70